B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap HydroLift VBR System
01 March 2010

MAR - 4 2010

COMPANY:	Aesculap®Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Matthew M. Hull 800-258-1946 (phone) 610-791-6882 (fax)
TRADE NAME:	Aesculap HydroLift VBR System
COMMON NAME:	Adjustable Vertebral Body Replacement Device
CLASSIFICATION NAME:	Spinal Vertebral Body Replacement Device
REGULATION NUMBER:	868.3060
PRODUCT CODE:	MQP

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the Aesculap HydroLift VBR System is substantially equivalent to:

1) SynEx Spacer System by Synthes (K003836)
2) Lift VB Spinal System by Medtronic Sofamor Danek, Inc. (K010930)

DEVICE DESCRIPTION

The Aesculap HydroLift VBR System is an adjustable vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. The center column of the device can be adjusted to the exact length required by the patients anatomy after implantation. Once it is adjusted to the desired length the column is mechanically locked in place. Primary components are manufactured from titanium alloy (Ti6Al4V).

INDICATIONS FOR USE

The Aesculap HydroLift VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The Aesculap HydroLift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. The Aesculap HydroLift VBR System may be used with bone graft. The Aesculap HydroLift VBR System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicates)

The Aesculap HydroLift VBR System is a mechanically adjustable vertebral body replacement device as are the predicates. The HydroLift's height is precisely adjusted using either a manual hydraulic pump or a mechanical distractor. Once the device is at the desired height locking screws are employed to fix that position. The Synthes SynEx Spacer uses a ratcheting cylinder with discreet increments (2.5mm) and endplates to adjust it's height. Medtronic SD's Lift VB uses a screw type center cylinder with two endplates to adjust it's height. All three devices utilize locking screws to secure the device once the desired height adjustment has been made. The HydroLift has pivoting endplates for precise lordotic angulation while the predicate devices offer a selection of endplates at set lordotic angles. The endplates of all three devices utilize small spikes and/or teeth to prevent migration. The material used for the Aesculap device is the same as that used to manufacture the predicate devices. Sterile saline solution serves as the fluid for the hydraulic mechanism.

PERFORMANCE DATA

Static and dynamic testing of the Aesculap HydroLift VBR System was performed in accordance with ASTM F1717 as recommended by the FDA Guidance for Spinal System 510(k)'s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 4 2010

Aesculap® Implant Systems, Inc.
% Mr. Matthew M. Hull, RAC
Manager, Regulatory Affairs
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K083186
Trade/Device Name: Aesculap HydroLift VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 31, 2009
Received: September 01, 2009

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K083186

Device Name:

Indications for Use:

The Aesculap HydroLift VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The Aesculap HydroLift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. The Aesculap HydroLift VBR System may be used with bone graft. The Aesculap HydroLift VBR System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083186 002